IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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Applicant	:	Durward I. Faries, Jr. et al.
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Title	:	Method and Apparatus for Monitoring Temperature of Intravenously Delivered Fluid and Other Medical Items

APPELLANT BRIEF

Mail Stop Appeal Brief-Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

This Brief is filed pursuant to the Notice of Appeal filed January 24, 2007.

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1. Real Party In Interest

The real party in interest is Medical Solutions, Inc., the assignee of the entire title and interest in and to the subject application by virtue of an assignment respectively recorded for parent application serial number 09/539,183 (now U.S. Patent No. 6,467,953) at the U.S. Patent and Trademark Office at Reel 011083, Frame 0874.

2. Related Appeals and Interferences

There are no related Appeals or Interferences.

3. Status of the Claimed Subject Matter

Claims 47-72 are pending in the application. Claims 1-46 have been canceled, and claims 6, 11 and 28-31 have been withdrawn from consideration as non-elected claims. Claims 47-49, 52, 54, 55, 58-61, 64, 66, 67, 69 and 70 stand rejected and are being appealed. Claims 50, 51, 53, 56, 57, 62, 63, 65 and 68 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. A complete copy of the pending claims appears in the attached Status of Claims appendix.

4. Status of Amendments

No amendment has been filed subsequent to the final rejection mailed October 30, 2006. Thus, the pending claims as listed in the attached Status of Claims appendix have not changed relative to their immediate prior version.

5. Summary of the Claimed Subject Matter

The claims on appeal are directed to medical devices and corresponding methods for visually indicating a temperature of a medical item placed within the device.

In particular, independent claim 47 recites a medical device for visually indicating a temperature of a medical item placed therein, where the device comprises a base and at least first and second panels attached to the base, a receptacle defined between the first and second panels for receiving the medical item within the receptacle, where the medical item has a particular temperature range for utilization, and a temperature sensor assembly to directly measure medical item temperature and visually indicate the measured medical item temperature (see, e.g., page 17, line 10, to page 19, line 6, and page 21, line 13, to page 23, line 21, and Figs. 9, 10 and 14-16). Claim 47 further recites that the medical device is configured such that any thermal treatment of the medical item received within the receptacle occurs only via heat transfer between the medical item and an external environment surrounding the medical device (see, e.g., page 4, lines 20-24, page 17, line 10, to page 18, line 15, and Figs. 9 and 10).

Similarly, independent claim 59 recites a method of visually indicating a temperature of a medical item placed in a medical device, where the medical device includes a base and at least first and second panels attached to the base and a receptacle defined between the first and second panels, the method comprising the steps of: (a) receiving the medical item within the receptacle defined between the first and second panels of the device, where the medical item has a particular temperature range for utilization; and (b) directly measuring medical item temperature and providing a visual indication of the measured medical item temperature via a temperature sensor assembly (see, e.g., page 17, line 10, to page 19, line 6, and page 21, line 13, to page 23, line 21, and Figs. 9, 10 and 14-16). Claim 59 further recites that the medical device is configured such that any thermal treatment of the medical item received within the receptacle occurs only via heat transfer between the medical item and an external environment surrounding the medical device (see, e.g., page 4, lines 20-24, page 17, line 10, to page 18, line 15, and Figs. 9 and 10).

Independent claim 71 recites a medical device for visually indicating a temperature of a medical item placed therein, where the medical device comprises a base and at least first and

second panels attached to the base, a receptacle defined between the first and second panels for receiving the medical item within the receptacle, where the medical item has a particular temperature range for utilization, and a temperature sensor assembly to directly measure medical item temperature and visually indicate the measured medical item temperature, where the temperature sensor assembly is affixed to one of the first panel, the second panel and the base (see, e.g., page 17, line 10, to page 19, line 6, and page 21, line 13, to page 23, line 21, and Figs. 9, 10 and 14-16).

Similarly, independent claim 72 recites a method of visually indicating a temperature of a medical item placed in a medical device, where the medical device includes a base and at least first and second panels attached to the base and a receptacle defined between the first and second panels. The method of claim 72 comprises: (a) receiving the medical item within the receptacle defined between the first and second panels of the device, where the medical item has a particular temperature range for utilization; and (b) directly measuring a medical item temperature and providing a visual indication of the measured medical item temperature via a temperature sensor assembly, where the temperature sensor assembly is affixed to one of the first panel, the second panel and the base (see, e.g., page 17, line 10, to page 19, line 6, and page 21, line 13, to page 23, line 21, and Figs. 9, 10 and 14-16).

The features of the remaining dependent claims 48-58 and 60-70 can also be found throughout the specification (see, e.g., page 7, lines 13-27, page 17, line 10, to page 19, line 6, page 21, line 13, to page 23, line 21, page 24, lines 9-26, page 26, line 20, to page 27, line 6, and Figs. 9, 10 and 14-16).

6. Grounds of Rejection to be Reviewed on Appeal:

The issues presented on Appeal are:

A. Whether claims 71 and 72 are properly rejected under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 5,875,282 to Jordan et al. (hereinafter referred to as "Jordan").

B. Whether claims 47-49, 52, 54, 55, 58-61, 64, 66, 67, 69 and 70 are properly rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 4,336,435 to Kashyap et al. (hereinafter referred to as "Kashyap") in view of Jordan.

C. Whether claims 71 and 72 are properly rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 5,989,238 to Ginsburg (hereinafter referred to as "Ginsburg") in view of Jordan.

7. Arguments:

A. Rejections Under 35 U.S.C. § 102(b)

35 U.S.C. §102(b) sets forth (in pertinent part):

"A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of the application for patent in the United States ..."

A claim is anticipated under any section of 35 U.S.C. § 102 only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference. See, e.g., *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). Thus, it follows that, if a prior art reference does not expressly or inherently describe each and every element of a claim, that claim cannot be anticipated by and thus cannot be rejected under 35 U.S.C. § 102(b) based upon such prior art reference.

1. Claims 71 and 72 are improperly rejected under 35 U.S.C. § 102(b) as being anticipated by Jordan.

Claim 71 recites a medical device for visually indicating a temperature of a medical item placed therein, where the medical device comprises a base and at least first and second panels attached to the base, a receptacle defined between the first and second panels for receiving the medical item within the receptacle, where the medical item has a particular temperature range for utilization, and a temperature sensor assembly to directly measure medical item temperature and visually indicate the measured medical item temperature, where the temperature sensor assembly is affixed to one of the first panel, the second panel and the base.

Similarly, claim 72 recites a method of visually indicating a temperature of a medical item placed in a medical device, where the medical device includes a base and at least first and

second panels attached to the base and a receptacle defined between the first and second panels. Claim 72 further recites that the method comprises: (a) receiving the medical item within the receptacle defined between the first and second panels of the device, where the medical item has a particular temperature range for utilization; and (b) directly measuring a medical item temperature and providing a visual indication of the measured medical item temperature via a temperature sensor assembly, where the temperature sensor assembly is affixed to one of the first panel, the second panel and the base.

Thus, each of claims 71 and 72 recites the feature of a temperature sensor assembly being affixed to one of a first panel, a second panel and a base of a medical device, where the temperature sensor assembly directly measures a medical item temperature and visually indicates the measured medical item temperature.

In contrast, Jordan discloses a warmer controller 10 that includes a temperature sensor 80 secured to a base or energy reservoir 88 (see Col. 7, lines 12-40 and Fig. 4 of Jordan), while a visual temperature display 34 is secured to a front face of the warmer controller (see Fig. 1 and Col. 6, lines 30-34 of Jordan). In other words, the temperature sensor 80 and the display 34 of Jordan are clearly secured on two separate panels or surfaces of the controller.

In rejecting claims 71 and 72 as being anticipated by Jordan (see paragraph 3, page 3 of the final Office Action mailed October 30, 2006), the Examiner construes the sensor 80, layers 82, stainless steel layer 84 and temperature adhesive layer 86 of Jordan as the recited temperature sensor assembly. The Examiner further asserts that these components of Jordan directly measure the temperature of a medical item 16 and provide a visual indication of the measured item temperature, and further that these items are affixed to a first panel or energy reservoir 88. However, the Examiner is incorrect in the assertion that the temperature sensor components 80, 82, 84, 86 of Jordan provide a visual indication of the temperature of the medical item 16. Rather, as noted above, and as clearly set forth in Jordan, warmer controller 10 includes a display 34 that is affixed to a front face of the warmer and not the energy reservoir 88.

Jordan therefore fails to disclose a temperature sensor assembly that directly measures a medical item temperature and visually indicates the measured item temperature and also that is secured to a single wall or panel (i.e., to one of the first panel, the second panel or the base) as

recited in each of claims 71 and 72. This rejection is therefore improper and should be withdrawn, since Jordan fails to disclose every recited feature of each of claims 71 and 72.

B. Rejections Under 35 U.S.C. §103(a)

35 U.S.C. §103(a) sets forth (in pertinent part):

> "(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains..."

The Supreme Court in Graham v. John Deere, 148 U.S.P.Q. 459 (1966), stated that the obviousness or non-obviousness of subject matter is determined in view of the scope and content of the prior art, the differences between the prior art and the claims at issue and the level of ordinary skill in the pertinent art. Secondary considerations, such as commercial success, long felt but unsolved needs, failure of others, etc., might be utilized to give light to the circumstances surrounding the origin of the subject matter sought to be patented. See M.P.E.P. §2141.

The following tenets of patent law must be adhered to when applying 35 U.S.C. §103:

(A) The claimed invention must be considered as a whole;

(B) The references must be considered as a whole and must suggest the desirability and thus the obviousness of making the combination;

(C) The references must be viewed without the benefit of impermissible hindsight vision afforded by the claimed invention; and

(D) Reasonable expectation of success is the standard with which obviousness is determined. Hodosh v. Block Drug Co., Inc., 229 U.S.P.Q. 182, 187 n.5 (Fed. Cir. 1986); See M.P.E.P. §2141.

The basic criteria to establish a *prima facie* case of obviousness, include: some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings; a reasonable expectation of success; and the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, not in applicant's disclosure. In re Vaeck, 20 U.S.P.Q.2d 1438 (Fed. Cir. 1991); See M.P.E.P. §2142. Three possible sources for a motivation to combine references include the nature of the problem to be solved, the teachings of the prior art, and the knowledge of persons of ordinary skill in the art. In re Rouffet, 47 U.S.P.Q.2d 1453, 1457-58 (Fed. Cir. 1998); See M.P.E.P. §2143.01.

1. Claims 47-49, 52, 54, 55, 58-61, 64, 66, 67, 69 and 70 are improperly rejected under 35 U.S.C. §103(a) as being unpatentable over Kashyap in view of Jordan

Claim 47 recites a medical device for visually indicating a temperature of a medical item placed therein, where the device comprises a base and at least first and second panels attached to the base, a receptacle defined between the first and second panels for receiving the medical item within the receptacle, where the medical item has a particular temperature range for utilization, and a temperature sensor assembly to directly measure medical item temperature and visually indicate the measured medical item temperature. Claim 47 further recites that the medical device is configured such that any thermal treatment of the medical item received within the receptacle occurs only via heat transfer between the medical item and an external environment surrounding the medical device.

Similarly, claim 59 recites a method of visually indicating a temperature of a medical item placed in a medical device, where the medical device includes a base and at least first and second panels attached to the base and a receptacle defined between the first and second panels, the method comprising the steps of: (a) receiving the medical item within the receptacle defined

between the first and second panels of the device, where the medical item has a particular temperature range for utilization; and (b) directly measuring medical item temperature and providing a visual indication of the measured medical item temperature via a temperature sensor assembly. Claim 59 further recites that the medical device is configured such that any thermal treatment of the medical item received within the receptacle occurs only via heat transfer between the medical item and an external environment surrounding the medical device.

Thus, each of claims 47 and 59 include the feature of the medical device being configured such that any thermal treatment of the medical item received within the receptacle occurs only via heat transfer between the medical item and an external environment surrounding the medical device.

In contrast, Kashyap teaches a microwave apparatus 4 for heating liquid in a container, including a bag holder 8 to support a blood or plasma bag, where the bag holder is disposed within a cavity 5 of the apparatus (see Col. 2, line 61, to Col. 3, line 68, and Fig. 2 of Kashyap). The bag holder 8 is mounted to a wall 25 of the apparatus with a rotatable shaft 9 (see Fig. 5 of Kashyap). In one embodiment (see Col. 3, lines 39-48, and Fig. 4 of Kashyap), the bag holder is in the form of an open box type structure 13 having a back wall 22, a side wall 23, and a flange 24 that covers one end of the holder so that the end of a plasma bag can be held securely within the holder. A temperature probe 30 can be mounted to shaft 9, which supports the bag holder, to contact a medical bag that is supported by the bag holder and heated within the cavity of the apparatus (see Col. 4, lines 10-51, and Figs. 6 and 7 of Kashyap).

In rejecting claims 47 and 59 as being obvious over Kashyap in view of Jordan (see paragraph 5, pages 4-5 of the final Office Action mailed October 30, 2006), the Examiner construes the bag holder 21 of Fig. 4 of Kashyap as the recited medical device of claims 47 and 59. In particular, the Examiner construes side wall 23, back wall 22 and flange 24 of the holder 21 of Kashyap as the recited base and at least first and second panels of claims 47 and 59. The Examiner construes the temperature sensor assembly 30 of Fig. 6 of Kashyap as a temperature sensor assembly to directly measure medical item temperature, and the Examiner further construes the microwave cavity 5, in which the bag holder 21 resides, as the recited external environment of claims 47 and 59. Appellants respectfully submit that this interpretation of the

bag holder 21 of Kashyap in an effort to reject claims 47 and 59 is unreasonable and improper for the following reasons.

The medical device taught in Kashyap is clearly the entire microwave apparatus 4 and not just the bag holder 21. Thus, it is unreasonable and improper to construe the bag holder 21, by itself, as a medical device or method of using a medical device as recited in claims 47 and 59, where the medical device visually indicates a temperature of a medical item placed therein. Clearly, the bag holder 21 of Kashyap, by itself, does not (and would not likely be modified to) visually indicate a temperature of a medical item placed in the bag holder.

The Examiner construes the bag holder 21 of Kashyap as the recited medical device in an effort to assert that the microwave cavity 5 (which is defined within the microwave apparatus 4) meets the limitation of the external environment as recited in claims 47 and 59. However, an interpretation of the bag holder 21 and microwave cavity 5 of Kashyap in the manner suggested by the Examiner still fails to anticipate the limitation of claims 47 and 59, which recites that the medical device is configured such that any thermal treatment of a medical item received within the receptacle of the medical device occurs only via heat transfer between the medical item and an external environment surrounding the medical device. Clearly, medical items placed within the bag holder 21 of Kashyap are heated by microwaves generated within cavity 5 by the microwave apparatus 4. Thus, thermal treatment of medical items placed within the bag holder 21 of Kashyap cannot occur only via heat transfer between the items and the environment surrounding the bag holder, since at least microwaves (which do not involve heat transfer) are clearly used to heat the items.

Further, the Examiner acknowledges that Kashyap does not teach the recited feature of a temperature sensor assembly to directly measure medical item temperature and visually indicate the measured medical item temperature. However, the Examiner asserts that providing such a visual indication to the bag holder 21 of Kashyap would have been obvious based upon the teachings of Jordan, since Jordan teaches a warmer controller including a temperature sensor with visual display. However, the Examiner has not provided a reasonable explanation as to where on the bag holder 21 of Kashyap a temperature indicator would be provided, other than

asserting that such a visual indication could be provided on the *"support structure/thermal treatment system"* of Kashyap (see page 5, lines 4-10 of the final Office Action).

The assertion that it would have been obvious to provide a visual indicator of temperature on any portion of the bag holder 21 of Kashyap (e.g., rather than an outside panel of the microwave apparatus 4) is unreasonable and improper. This further indicates the unreasonable position taken by the Examiner in construing an internal component of the microwave oven (rather than the microwave oven itself) of Kashyap as a medical device for visually indicating a temperature of a medical item placed within the device as recited in claims 47 and 59. Placing a visual temperature indicator on the bag holder 21 would likely be ineffective and of little or no use to an operator of the microwave apparatus 4, since the bag holder 21 is disposed within the microwave cavity 5 and thus cannot be easily viewed or may not be viewable at all by the operator during use of the microwave apparatus. Therefore, contrary to the Examiner's assertion, there would be no motivation to provide a visual temperature indicator to the bag holder of Kashyap as suggested by the Examiner.

For all of the foregoing reasons, there is no combination of Kashyap with Jordan that renders obvious claims 47 and 59. Accordingly, the rejection of claims 47 and 59 as being obvious based upon the combination of Kashyap and Jordan is improper and should be withdrawn.

Claims 48, 49, 52, 54, 55, 58, 60, 61, 64, 66, 67, 69 and 70 depend, directly or indirectly, from claim 47 or claim 59. Therefore, in light of the previous remarks, the rejection of these claims as being obvious over Kashyap in view of Jordan is improper and should also be withdrawn.

2. Claims 71 and 72 are improperly rejected under 35 U.S.C. §103(a) as being unpatentable over Ginsburg in view of Jordan.

As noted above, claims 71 and 72 recite a medical device and corresponding method for visually indicating a temperature of a medical item placed therein. In particular, each of claims 71 and 72 recite the feature of a temperature sensor assembly being affixed to one of a first panel, a second panel and a base of a medical device, where the temperature sensor assembly

directly measures a medical item temperature and visually indicates the measured medical item temperature.

Ginsburg teaches an infusion system 10 including a chamber 28 to receive a bag or reservoir 30 of fluid, a thermistor 34 in contact with the reservoir 30 to monitor the temperature of fluid within the reservoir, and a screen 24 to provide information about the set points for volume, infusion rate and temperature of the fluid (see Col. 4, line 34, to Col. 5, line 17, and Figs. 1 and 2 of Ginsburg). As can be seen from Figs. 1 and 2 of Ginsburg, the thermistor 34 and the screen 24 are clearly on different panels or surfaces of the system housing.

In rejecting claims 71 and 72 (see paragraph 6, pages 5-6 of the final Office Action mailed October 30, 2006), the Examiner construes the base, at least first and second panels, and receptacle as recited in the claims as the walls of system 10 and chamber 28 of Ginsburg. The Examiner acknowledges that Ginsburg fails to teach a temperature sensor assembly as recited in claims 71 and 72, where the temperature assembly includes the feature of measuring a medical item temperature and visually indicating the measured medical item temperature.

However, the Examiner relies upon Jordan (discussed above) to assert that it would have been obvious to provide such a feature to Ginsburg. Even assuming that it would be reasonable to provide such a visual temperature indicator to Ginsburg based upon the teachings of Jordan, the combination would still fail to meet every recited limitation of claims 71 and 72. This is because both Ginsburg and Jordan fail to teach a temperature sensor assembly that directly measures a medical item temperature and visually indicates the measured item temperature and further still that is secured to a single wall or panel (i.e., one of the first panel, the second panel and the base) as recited in claims 71 and 72.

Thus, any combination of Ginsburg with Jordan still fails to teach every limitation of claims 71 and 72. The Examiner has therefore failed to meet the *prima facie* burden in asserting claims 71 and 72 are obvious over Ginsburg in view of Jordan. Accordingly, the rejection of claims 71 and 72 as being obvious over these two references is improper and should be withdrawn.

In view of the foregoing it is submitted that the rejections of claims 47-49, 52, 54, 55, 58-61, 64, 66, 67 and 69-72 are improper and should be reversed.

Respectfully submitted,

/Andrew J. Aldag/
Andrew J. Aldag
Registration No. 40,483

EDELL, SHAPIRO & FINNAN, LLC
1901 Research Boulevard, Suite 400
Rockville, Maryland 20850-3164
(301) 424-3640

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8. Claims Appendix

1 – 46. (Canceled)

47. A medical device for visually indicating a temperature of a medical item placed therein comprising:

a base and at least first and second panels attached to said base;

a receptacle defined between said first and second panels for receiving said medical item within said receptacle, wherein said medical item has a particular temperature range for utilization; and

a temperature sensor assembly to directly measure medical item temperature and visually indicate said measured medical item temperature;

wherein said medical device is configured such that any thermal treatment of said medical item received within said receptacle occurs only via heat transfer between said medical item and an external environment surrounding said medical device.

48. The medical device of claim 47 wherein said temperature sensor assembly includes a temperature sensor disposed within said first panel to directly measure said medical item temperature.

49. The medical device of claim 48 wherein said receptacle is configured to enable said medical item to be in thermal relation with said temperature sensor in said first panel to facilitate temperature measurement.

50. The medical device of claim 47 wherein said temperature sensor assembly includes a plurality of temperature sensitive substances each associated with a corresponding temperature range, wherein each said substance is responsive to a temperature of said medical item and provides a visual indication of said medical item temperature when said medical item temperature is within said corresponding temperature range.

51. The medical device of claim 47 wherein said temperature sensor assembly includes a temperature sensing strip providing a digital indication of said medical item temperature.

52. The medical device of claim 47 wherein said temperature sensor assembly includes a display to visually indicate said medical item temperature.

53. The medical device of claim 47 wherein said first panel includes a handle to facilitate transport and handling of said medical device.

54. The medical device of claim 47 wherein said medical device is attached to a support structure.

55. The medical device of claim 47 wherein said medical device is attached to a thermal treatment system.

56. The medical device of claim 52 wherein said display includes a liquid crystal display.

57. The medical device of claim 47 wherein said temperature sensor assembly includes a voice synthesizer to provide an audio indication of said medical item temperature.

58. The medical device of claim 47 wherein said temperature sensor assembly includes an infra-red temperature sensor.

59. A method of visually indicating a temperature of a medical item placed in a medical device, wherein said medical device includes a base and at least first and second panels

attached to said base and a receptacle defined between said first and second panels, said method comprising the steps of:

(a) receiving said medical item within said receptacle defined between said first and second panels of said device, wherein said medical item has a particular temperature range for utilization; and

(b) directly measuring medical item temperature and providing a visual indication of said measured medical item temperature via a temperature sensor assembly;

wherein said medical device is configured such that any thermal treatment of said medical item received within said receptacle occurs only via heat transfer between said medical item and an external environment surrounding said medical device.

60. The method of claim 59 wherein said temperature sensor assembly includes a temperature sensor disposed within said first panel, and step (b) further includes:

(b.1) directly measuring said medical item temperature via said temperature sensor.

61. The method of claim 59 wherein said receptacle is configured to enable said medical item to be in thermal relation with said temperature sensor in said first panel to facilitate temperature measurement.

62. The method of claim 59 wherein said temperature sensor assembly includes a plurality of temperature sensitive substances each associated with a corresponding temperature range, wherein each said substance is responsive to a temperature of said medical item, and step (b) further includes:

(b.1) measuring and visually indicating said medical item temperature via each temperature sensitive substance when said medical item temperature is within a corresponding temperature range of that substance.

63. The method of claim 59 wherein said temperature sensor assembly includes a temperature sensing strip, and step (b.1) further includes:

(b.1.1) measuring said medical item temperature and providing a digital indication of said measured temperature via said temperature sensing strip.

64. The method of claim 59 wherein said temperature sensor assembly includes a display, and step (b) further includes:

(b.1) visually indicating said medical item temperature via said display.

65. The method of claim 59 wherein said first panel includes a handle, and step (a) further includes:

(a.1) transporting and handling said medical device via said handle.

66. The method of claim 59 wherein step (a) further includes:

(a.1) attaching said medical device to a support structure.

67. The method of claim 59 wherein step (a) further includes:

(a.1) attaching said medical device to a thermal treatment system.

68. The method of claim 59 wherein step (b) further includes:

(b.1) providing an audio indication of said medical item temperature via a voice synthesizer.

69. The medical device of claim 47, wherein said temperature sensor assembly is affixed to one of said first panel, said second panel and said base.

70. The method of claim 59, wherein said temperature sensor assembly is affixed to one of said first panel, said second panel and said base.

71. A medical device for visually indicating a temperature of a medical item placed therein comprising:

a base and at least first and second panels attached to said base;

a receptacle defined between said first and second panels for receiving said medical item within said receptacle, wherein said medical item has a particular temperature range for utilization; and

a temperature sensor assembly to directly measure medical item temperature and visually indicate said measured medical item temperature, wherein said temperature sensor assembly is affixed to one of said first panel, said second panel and said base.

72. A method of visually indicating a temperature of a medical item placed in a medical device, wherein said medical device includes a base and at least first and second panels attached to said base and a receptacle defined between said first and second panels, said method comprising the steps of:

(a) receiving said medical item within said receptacle defined between said first and second panels of said device, wherein said medical item has a particular temperature range for utilization; and

(b) directly measuring a medical item temperature and providing a visual indication of said measured medical item temperature via a temperature sensor assembly, wherein the temperature sensor assembly is affixed to one of the first panel, the second panel and the base.

9. Evidence Appendix – None

10. Related Proceedings Appendix - None